REMARKS

The following comments are responsive to the Non-final Office Action of May 5, 2009 ("Action"). Reconsideration and allowance are respectfully requested based on the above amendments and the below remarks.

References Not Considered in IDS

Accompanying the Action, the Office lined through multiple references of form PTO/SB/08a of the IDS' filed February 25 and 26, 2009 indicating that they were not considered. The lined through references were electronically provided to and received by the Office when the respective IDS' were filed as indicated by the respective Electronic Acknowledgement Receipts. The Action does not indicate that these references were not received. Accordingly, Applicants respectfully request that the Office consider all of the references provided in the IDS' and indicate as such in the subsequent office action.

Claim Rejections Under 35 U.S.C. §§ 102 and 103

Claims 1-11, 13-21, 23, and 43-46 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Fischell, U.S. Patent No. 6,128,538 ("Fischell"), or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Fischell. Applicants respectfully traverse for at least the following reasons.

In order to further clarify the claimed invention, claim 1 has been amended in this response to expedite prosecution. Claim 1, as amended, recites "(e) preventing the therapy device from delivering therapy to the patient for a predetermined quantity of block counts after the therapy device has been activated to allow the seizure detection algorithm to stabilize by monitoring the patient for the predetermined quantity of block counts to establish background data for nervous system disorder detection; and (f) processing the neurological signal by the seizure detection algorithm, after stabilization, to detect whether a nervous system disorder has occurred using the background data." It is respectfully submitted that Fischell does not disclose this combination of claim features. In fact, Fischell makes no mention of stabilizing a detection algorithm – indeed the terms stable or stabilize are not found in Fischell. Instead, Fischell merely points out that the detection algorithm may be set so it will not immediately react to a

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single sensed signal but instead will wait until there are a sufficient number of sensed signals so as to avoid providing a false positive. This falls short of disclosing the recited stabilizing of the detection algorithm. Furthermore, there is nothing in Fischell (or anything else of record) to suggest that the detection algorithm of Fischell requires or would benefit from a stabilizing period.

Moreover, Fischell does not teach or suggest stabilizing an algorithm for nervous system disorder detection by establishing background data during a predetermined quantity of block counts, and then, after stabilization, detecting whether a nervous system disorder has occurred using the background data. An example of these features of claim 1 is described in the seizure detection algorithm in figure 8 of the application as filed. *See also*, paras. 62, 123, and 137-144. Figure 8 includes a foreground determinator 805, a background determinator 807, module 811, and a Detection Criteria Module 813. In paragraph 137, the application describes a start-up period where a seizure detection algorithm stabilizes to adjust to data from an individual to establish a background to avoid potential erroneous decisions. In paragraph 62, the foreground determinator 805 and the background determinator 807 respectively provide values from foreground and background intervals. In the example of figure 8, module 811 may determine a ratio of inputs received from the foreground determinator 805 and the background determinator 807. The Detection Criteria Module 813 receives the ratio and determines whether an event is detected.

In the rejection, the Action cites column 19, lines 19-33 of Fischell as allegedly disclosing stabilizing in the manner claimed. Applicants respectfully disagree. Fischell merely describes detecting a neurological event based on whether squared EEG signals have exceeded a threshold a certain number of times during a time interval T, but does not describe stabilizing an algorithm for neurological event detection during the time interval T by establishing background data from the squared EEG signals, and then, after stabilization, detecting whether a nervous system disorder has occurred using the background data. More specifically, the cited lines of Figures refer to "schemes for detecting an event." Fischell explains that

> "[i]f the amplitude of the sum of the time synchronized squared EEG signals 355 exceeds the event detection threshold 369 as shown in FIG. 5D . . ., the algorithm 368 sends a positive event detected message 358 to the event density counter/detector algorithm 371. The event density counter/detector algorithm 371 determines if there have been enough events in the most recent time period 'T' to notify the central processor 51 with the event identified message 372 indicating

that an event has really occurred. A typical time period 'T' would be approximately 2 seconds but could be in the range from 1/2 to 100 seconds. The event density counter/detector algorithm 371 will reduce the number of false positive event identifications by eliminating short uncorrelated EEG bursts."

See Fischell at C19, L14-23.

Thus, Fischell is merely concerned with the number of times a squared EEG signal exceeds a threshold in a most recent period T (*see* Fischell, C19, L14-33), but does not teach or suggest stabilizing an algorithm for neurological event detection by establishing background data using the squared EEG signals during a time period T, and then, after stabilization, detecting whether a nervous system disorder has occurred using the background data. As such, Fischell does not disclose, inherently or otherwise, at least the above recited features in paragraphs (e) and (f) of claim 1. Therefore, for at least this reason, Fischell does not anticipate independent claim 1 under 35 U.S.C. §102(b) and is allowable.

Next, the Office Action goes on to say that in the alternative, it would have been obvious to have the algorithm stabilize as it is allegedly well known to do so and therefore independent claim 1 is unpatentable over Fischell under 35 U.S.C. §103(a). Applicants respectfully disagree with the Office Action's assertion.

Applicants respectfully submit that Office Action's statement is conclusory because no support has been provided to show why it would be obvious to include a stabilizing period in the detection algorithm of Fischell. The Office Action merely states on Page 4 "It is obvious and well known to have some time for the algorithm to stabilize such as 2 seconds so the algorithm can correctly detect a seizure." Applicants respectfully disagree. As stated above, Fischell makes no mention of stabilizing a detection algorithm.

Moreover, Applicants respectfully submit that the Office Action has not satisfied the requirement of providing a logical rationale to support the rejection. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) ("To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). Importantly, there has been no support provided that shows the detection algorithm of Fischell could be stabilized or that it would benefit from stabilizing.

Moreover, the arguments in section 21 of the Action do not provide a rationale to support the rejection. *See* Action, p. 8. In section 21, the Action argues that the event density counter determines if there are enough events in a most recent time period to determine that an event has occurred to eliminate false positives. *Id.* Notably, the Action comments on "signal" stabilization, and alleges that a stabilized signal effectively stabilizes the detection algorithm of Fischell. *Id.* Applicants respectfully disagree.

The reasoning set forth in the Action is unsupported as the citation to Fischell lacks any discussion of signal instability. Fischell explains that "event density counter/detector algorithm 371 will reduce the number of false positive event identifications by eliminating short uncorrelated EEG bursts." *See* Fischell, C19, L14-33. Thus, false positives in Fischell occur from identifying a neurological event where an insufficient number of EEG signals cross a threshold during a time period T. *Id.* Contrary to the assertion made in the Action, the cited lines of Fischell lack discussion of EEG signal instability, and hence Fischell also fails to disclose stabilizing an EEG signal leading to stabilization of the detection algorithm. Thus, any suggestion that it would be obvious to include the above recited feature of claim 1 necessarily lacks support. Accordingly, Fischell does not support a *prima facie* case of obviousness with respect to claim 1 and claim 1 is patentably distinct in view of Fischell.

Independent claims 14, 43, and 45 recite features similar to the features discussed above with respect to claim 1 and, therefore, are patentably distinct over Fischell for at least the reasons that claim 1 is patentably distinct.

The pending claims that depend from one of independent claims 1, 14, 43, and 45 are patentably distinct for at least the reasons that the independent claims 1, 14, 43, and 45 are patentably distinct and for the additional features recited therein.

Claims 28-29, 32, and 37-38 stand rejected under 35 U.S.C. §§ 102(e) and 103(a) as being unpatentable over Snell (US 2002/0143372). Applicants respectfully traverse for at least the following reasons.

Independent claims 28, 29, 32, 37, and 38 recite features similar to the features "determining whether the programming information can result in delivery of therapy with a number of stimulations per detection being above a predetermined limit of stimulations per detection" and "preventing the therapy device from being configured according to the

programming information if it could result in delivery of a number of stimulations per detection above the predetermined limit of stimulations per detection" as recited in claim 28.

In the Action, the Action refers to paragraph 46 of Snell to reject independent claims 28, 29, 32, 37, and 38. *See* Action, p. 6. In paragraph 46, Snell describes that "if a programming parameter associated with device sensitivity is outside the range of acceptable levels of sensitivity, then an error signal is returned to the transmitting device." Snell further notes that "a wide variety of error detection techniques may be employed depending upon the particular parameters being reprogrammed and no attempt is made herein to provide an exhaustive list." *See* Snell, ¶46.

Paragraph 46 of Snell does not, however, teach or suggest either of the claimed determining or preventing. Notably, Snell's disclosure of a range of acceptable levels of sensitivity for device allows a "physician to specify the sensitivity with which the device senses electrical signals within the heart" (*see* Snell, ¶4), such as to detect a "natural sinus rhythm of the heart" (*id.* at ¶39), but does not teach or suggest that there is a "number of stimulations per detection being above a predetermined limit of stimulations per detection" for Snell's device. Moreover, Snell's error signal does not prevent its device from being configured according to programming information if it could result in delivery of a number of stimulations per detection above the predetermined limit of stimulations per detection. Thus, Snell does not teach or suggest either of the claimed determining or preventing. Further, the Action appears to implicitly acknowledge that Snell is not an anticipatory by taking an alternative position and conceding that Snell does not teach all of the features of claim 28. *See* Action, p. 6, *stating* "Snell does not expressly state that it checks for stimulations per detection period, stimulations per detection cluster, or on time." According, Applicants respectfully request withdrawal of the rejection of claims 28, 29, 32, 37, and 38 under 35 U.S.C. § 102.

Next, the Action fails to establish a *prima facie* case of obviousness to reject claims 28, 29, 32, 37, and 38. The Action improperly relies on Applicants' disclosure to find that Snell suggests the features the Action concedes Snell lacks. The Office Action asserts that Snell

states that the system can use a wide variety of error detection techniques depending upon the particular parameters that are set and they did not list the particular parameters or error checking techniques as the list was so exhaustive.

See Action, p. 6. The Action alleges that it would have

been obvious to one having ordinary skill in the art at the time of the invention to have used the error handling techniques of Snell to look at the programmable parameters associated with stimulations per detection period, stimulations per detection cluster, and on time to provide the predictable results of checking the programmable parameters to

make sure that they are within thresholds to make sure that the patient, device and battery are not harmed.

Id. at p. 6-7.

Thus, the Action attempts to establish a *prima facie* case of obviousness using Applicants' disclosure. This is improper hindsight analysis. Without Applicants' disclosure, one of ordinary skill in the art would not modify Snell's device that has a range of acceptable levels of electrical signal sensitivity to determine a "number of stimulations per detection being above a predetermined limit of stimulations per detection" for Snell's device." The mere fact that Snell alleges that "a wide variety of error detection techniques may be employed" (*see* Snell, ¶ 46) does not suggest that one of ordinary skill in the art would modify Snell in the manner claimed. The Action is improperly using hindsight analysis and relying on Applicants' disclosure to allege Snell renders obvious claims 28, 29, 32, 37, and 38. Thus, the Action has failed to establish a *prima facie* case of obviousness. According, Applicants respectfully request withdrawal of the rejection of claims 28, 29, 32, 37, and 38 under 35 U.S.C. § 103.

Claims 47 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Snell in view of Archer, U.S. Patent No. 6,690,974. Applicants respectfully traverse for at least the following reasons.

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Claims 47 and 48 ultimately depend from independent claim 29 and are therefore patentably distinct for at least the reasons as independent claim 29 and for additional features recited therein.

Conclusion

The claims as now presented are believed to be in allowable condition. Applicants respectfully request consideration of the application and allowance of all pending claims. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

Respectfully submitted,

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By:/William J. Allen/
William J. Allen
Registration No. 51,393
BANNER & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, IL 60606
Telephone: 312-463-5000
Facsimile: 312-463-5001